

6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-5188

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9/27/49

August 18, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug and Cosmetic Act that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

<u>C 500mg XTRA:</u> For healthy immune function. This advanced formula features Vitamin C-500 blended with bioflavonoids, including hesperidin and rutin, as well as zinc. These ingredients work in harmony to help promote healthy immune function, capillary strength and provide antioxidant protection for healthy cells, tissues and overall well-being.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

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Sincerely,

Deborah Shur Trinker

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Vice President of Regulatory Affairs and Assistant General Counsel

Enclosure